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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/747,832	12/29/2003	David L. Thompson	11738.00214	6454
70467 7590 12/11/2007 BANNER & WITCOFF, LTD AND ATTORNEYS FOR CLIENT NUMBER 011738 10 SOUTH WACKER DRIVE SUITE 3000 CHICAGO, IL 60606			EXAMINER MENDEZ, MANUEL A	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 12/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/747,832

Applicant(s)

THOMPSON, DAVID L.

Examiner

Manuel Mendez

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-206 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 14-206 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 14-43, drawn to an iontopheretic sensor module for sampling and detecting a concentration of a substance of interest through skin, wherein the sensor module comprises a sampling system and a concentration determining system; a control system, responsive to the iontopheretic sensor module, for determining a response to the sampled and determined concentration of a substance of interest; a sensor telemetry system for transmitting information regarding the response determined by the control system through the patient's body; a pump telemetry system for receiving information regarding the response determined by the control system through the patient's body and for communicating the information to an implantable drug pump; and an implantable drug pump, acting in response to the information communicated to the implantable drug pump from the pump telemetry system, to deliver a responsive dose of an appropriate medicament to the patient, classified in class 604, subclass 20.

II. Claims 44-71, drawn to a sensor module for sampling and determining the concentration of a substance of interest including glucose in the patient; a control system for determining an appropriate response to the determined concentration of the substance of interest; an implantable drug pump for dispensing an appropriate amount of a medicament including insulin to the patient; means for communicating information from the sensor module to the control system; and, means for communicating information from the control system to the implantable drug pump, classified in class 604, subclass 65.

III. Claims 72-99, drawn to a sensor for sampling and determining the concentration of a substance of interest including glucose in the patient; a control system for determining an appropriate response to the determined concentration of the substance of interest; an implantable drug pump for dispensing an appropriate amount of a medicament including insulin to the patient; a first communications system capable of communicating information, regarding the sensed concentration of a substance of interest in the patient, from the sensor to the control system; and, a second communications system capable of communicating information, regarding the determined response to the determined concentration of the substance of interest, from the control system to the implantable drug pump, classified in class 604, subclass 66.

IV. Claims 100-102, drawn to an external, disposable, reusable sensor for sampling and determining the concentration of a substance of interest including glucose in the patient; a control system including a microprocessor for determining an appropriate response to the determined concentration of the substance of interest,

wherein the microprocessor operates a program including the steps of receiving information related to the concentration of the substance of interest, comparing the information related to the concentration to information related to a predetermined limit, and then, if the comparing step indicates the concentration exceeds the predetermined limit, determining the appropriate response to the determined concentration, and generating information to cause the drug pump to deliver the responsive dose of the appropriate medicament, and if the comparing step indicates the concentration does not exceed the predetermined limit, waiting for a period of time to expire before again operating the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit, in which the periodicity of the operation of the program, including the period of time for waiting, may be present in the program or programmed, and in which the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on command, in which the microprocessor further includes one of either a memory with a look-up table or a formula for the responsive dose of the appropriate medicament or a memory, and the step of determining the responsive dose includes one of retrieving a value from the look-up table or determining the dose according to the formula; an implantable drug pump for dispensing an appropriate amount of a medicament including insulin to the patient, in which the drug pump includes memory, and the information communicated to the pump to cause the drug pump to deliver the responsive dose of the appropriate medicament is stored in the memory with related time of the delivery of the responsive dose, and the memory keeps the information and time available for later uplink telemetry; uplink telemetry equipment including an operatively connected antenna which receives downlinked telemetry programming data transmitted by an external programmer; a first communications system capable of communicating information, regarding the sensed concentration of a substance of interest in the patient, from the sensor to the control system; and, a second communications system capable of communicating information, regarding the determined response to the determined concentration of the substance of interest, from the control system to the implantable drug pump; and an operatively connected battery, classified in class 604, subclass 67.

V. Claim 103-107, drawn to a sensor module for sampling and determining the concentration of a substance of interest including glucose in the patient; a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being integrally connected to the sensor module; an implantable drug pump for dispensing an appropriate amount of a medicament including insulin to the patient; and a telemetry system for communicating information from the control system to the implantable drug pump, classified in class 424, subclass 424.

X. Claims 108-135, drawn to an iontopheretic sensor module for sampling and detecting a concentration of a substance of interest through skin; a control system, responsive to the iontopheretic sensor module, for determining a response to the sampled and determined concentration of a substance of interest; a sensor telemetry system for transmitting information regarding the response determined by the control system through the patient's body; a pump telemetry system for receiving information regarding the response determined by the control system through the patient's body and for communicating the information to an implantable drug pump; and an implantable drug pump, acting in response to the information communicated to the implantable drug pump from the pump telemetry system, to deliver a responsive dose of an appropriate medicament to the patient, classified in class 604, subclass 19.

XI. Claims 136-163, drawn to a sensor module for sampling and determining the concentration of a substance of interest in the patient; a control system for determining an appropriate response to the determined concentration of the substance of interest; an implantable drug pump for dispensing an appropriate amount of a medicament to the patient; means for communicating information from the sensor module to the control system; and, means for communicating information from the control system to the implantable drug pump., classified in class 128, Digest 13.

XII. Claims 164-191, drawn to a sensor for sampling and determining the concentration of a substance of interest in the patient; a control system for determining an appropriate response to the determined concentration of the substance of interest; an implantable drug pump for dispensing an appropriate amount of a medicament to the patient; a first communications system capable of communicating information, regarding the sensed concentration of a substance of interest in the patient, from the sensor to the control system; and, a second communications system capable of communicating information, regarding the determined response to the determined concentration of the substance of interest, from the control system to the implantable drug pump, classified in class 604, subclass 131.

XIII. Claim 192-195, drawn to a sensor module for sampling and determining the concentration of a substance of interest in the patient; a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being integrally connected to the sensor module; an implantable drug pump for dispensing an appropriate amount of a medicament to the patient; and a telemetry system for communicating information from the control system to the implantable drug pump, classified in class 604, subclass 151.

XVII. Claims 196-206, drawn to means for determining the concentration of a substance of interest in the patient; means for determining an appropriate response to the determined concentration of the substance of interest; a medical device for taking an action appropriate to a concentration of interest in a patient; means for communicating information from the means for determining the concentration to the means for determining an appropriate response; and, means for communicating information from the means for determining an appropriate response to the medical device, classified in class 604, subclass 67.

The inventions are distinct, each from the other because of the following reasons:

Inventions I to XVII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, the subcombination groups disclosed above has separate utility in view of the structural differences identified in each of the Groups. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read 'Manuel Mendez', with a stylized, cursive script.

Manuel Mendez
Primary Examiner
Art Unit 3763

MM